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(54) Title: THIN-FILM METAL ALLOY BIOMEDICAL IMPLANTABLE DEVICES

(57) Abstract: A device designed for implantation into a body to control fluid flow through a lumen in a body that includes at least one leaflet adapted to be located within the lumen. The leaflet(s) include(s) an anchor portion that remains substantially stationary within the lumen and a seal portion that is movable between open and closed positions. The leaflet(s) are made from a thin-film metal alloy that has a thickness which is less than 50 microns.

THIN-FILM METAL ALLOY BIOMEDICAL IMPLANTABLE DEVICES

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to biomedical devices, such as heart valves, that are designed for implantation in individuals and use over relatively long periods of time. More particularly, the present invention involves the use of thin films of metal alloys in such biomedical devices.

2. Description of Related Art

[0002] The first mechanical prosthetic valve was implanted surgically in 1952. Over the years more than 30 different mechanical designs have originated worldwide. These valves have progressed from a simple caged ball valve to modern titanium bi-leaflet mechanical valves. Additionally, tissue valves are harvested from animals, fixed in order to denature proteins (which would otherwise illicit an immune response), and mounted on a variety of sewing rings. A few of the noteworthy, surgically-implanted and catheter-implanted valves include: the Dobben valve (U.S. Patent No. 4,994,077, a wire/disk valve), the Vince valve (U.S. Patent No. 5,163,953, a stent/coil valve), the Teitelbaum valve (U.S. Patent No. 5,397,351, self-expanding, percutaneously-delivered), the Taheri valve (U.S. Patent No. 5,824,064, aortic valve replacement with arch graft), the Anderson valve (U.S. Patent No. 5,411,552, balloon expandable percutaneously inserted valve), the Jayaraman valve (U.S. Patent No. 5,855, 597, star-shaped catheter-inserted valve), the Besselver valve (U.S. Patent No. 5,855,601, catheter-based, stent-valve) and the Carpenter-Edwards valve which is part of a family of surgically-placed valves that attempt to mimic the semi-lunar nature of the body's aortic and pulmonary valves.

[0003] Surgical valve replacements are accomplished only via the use of a median sternotomy and cardiopulmonary bypass. In the past decade, newly engineered "valved stents" have been used successfully in animal experiments

and in limited human trials. For example, see Bonhoeffer, P., Boudjemaline, Y., *et al.* Transcatheter replacement of a bovine valve in the pulmonary position: a lamb study (*Circulation* 2000, 102:S13:S16) and Bonhoeffer, P., Boudjemaline, Y., *et al.* Percutaneous replacement of a pulmonary valve in a right ventricle to pulmonary artery conduit (*Lancet* 2000, 356:1403-1405). Thus, while the ability to achieve a percutaneous, or non-surgical or catheter-based, valve replacement has arrived, the devices presently used for both aortic and pulmonary valve replacements are excessively large and will likely have poor long-term function. The Bonhoeffer Valve from NuMed incorporates a paraffin-fixed bovine venous valve into a collapsible stent. This device is extremely bulky (about 6mm diameter) for percutaneous delivery in smaller patients and utilizes a venous valve that may quickly deteriorate in the arterial circulation. Similar devices utilize polytetrafluoroethylene (PTFE) (GORTEX) for the construction of valve leaflets. These devices are also exceedingly bulky, and their PTFE is likely to quickly calcify and stiffen *in vivo*.

[0004] Of the surgically placed prosthetic valves, there is much room for improvement. Many mechanical valves are thrombogenic even with coumadin anticoagulation. Other prosthetic valves have limited longevity and many tissue valves can calcify and become progressively stenotic. Accordingly, there is an immediate need for a replacement valve constructed with a durable low profile material that is able to overcome these problems.

SUMMARY OF THE INVENTION

[0005] The present invention covers the use of thin films of phase transforming metal alloys or twin boundary motion metal alloys, such as NiTi alloys, in valves that are used in surgical or non-surgical human heart-valve or other valve replacement. The use of thin films of these types of materials allows for the development of low profile, durable, collapsible valves that are able to be delivered via a catheter or implanted by a surgeon. A feature of this invention is to take advantage of the size, durability, fatigue resistance, biocompatibility and shape-memory of thin films of metal alloys (known as phase transforming and twin boundary motion metal alloys or materials) by using these super-elastic thin

films to form prosthetic valve leaflets. Presently, prosthetic valves are available for either surgical or catheter-delivered placement. None of the valves presently commercially available (or in development) use thin films of metal alloys to form valve leaflets or any other components.

[0006] In accordance with the present invention, a device is provided that is designed for implantation into a body to control fluid flow through a lumen in the body, such as an artery, vein or other cardiovascular component including surgically placed conduits. The device includes at least one leaflet adapted to be located within the lumen. The leaflet includes an anchor portion that remains substantially stationary within the lumen and a seal portion that is movable between an open position wherein fluid flow through the lumen in a given direction is allowed and a closed position wherein the flow of fluid through the lumen in a direction opposite to the given direction is restricted. As a feature of the present invention, the leaflet(s) is (are) made from a film of metal alloy that has a thickness which is less than 50 microns.

[0007] The lumen into which the device is to be implanted includes a lumen wall that defines an opening having a periphery and a center. In one embodiment of the present invention, the seal portion of the leaflet moves towards the center of the lumen opening when the leaflet moves to the closed position. In another embodiment of the invention, the seal portion of the leaflet moves towards the periphery of the lumen opening when the leaflet moves to the closed position.

[0008] Thin films of phase transforming and twin boundary motion metal alloys provide advantages in the construction of both surgically and percutaneously placed valves. In the case of catheter-based valves, thin-film metal alloys allow the construction of a heart valve that is able to collapse to 2-3 mm in diameter. Additionally, the shape-memory features of phase transforming and twin boundary motion metal alloys allow this device to expand and regain the form of a functional heart valve. Finally, the biocompatible and non-thrombogenic nature of these metal alloys also lends to advantages in the construction of this sort of valve.

[0009] The above discussed and many other features and attendant advantages of the present invention will become better understood by reference to the detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a diagrammatic sectional representation showing the operation of one embodiment of a valve in accordance with the present invention where the valve leaflets move inward toward the lumen center during closing of the valve.

[0011] FIG. 2 is a diagrammatic sectional representation showing the operation of a second embodiment of a valve in accordance with the present invention where the valve leaflets move outward toward the lumen walls during closing of the valve.

[0012] FIG. 3 shows one exemplary embodiment of a thin film that is formed into a valve having three leaflets that move inward during valve closure.

[0013] FIGS. 4A-4C show the three main elements of a valve in accordance with the embodiment shown in FIG. 2 where a thin film (4C) is formed into two leaflets that move outward during valve closure.

[0014] FIG. 5 is a top view of a partially assembled valve in which the two structural elements shown in FIGS. 4A and 4B have been combined.

[0015] FIG. 6 is a top view of a complete valve assembly where the thin film (4C) has been anchored within the partially assembled valve shown in FIG. 5. The valve assembly is shown in the open position.

[0016] FIG. 7 is a top view of the valve assembly shown in FIG. 6 where the valve is shown in the closed position.

[0017] FIG. 8 is a diagrammatic view of an exemplary system for making thin films of metal alloy that can be used to form thin films in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] A first exemplary embodiment of a stent-based transcatheter heart valve in accordance with the present invention is shown in FIG. 1. The heart valve is shown in the open position at 10 and the closed position at 12. The valve is designed for implantation into a body to control fluid flow through arteries and other vessels or lumens located in the body. The heart valve includes a thin film 13 of phase transforming material or twin boundary motion material that is used to form two leaflets 14, 16 and a body 18. The leaflets 14 and 16 include anchor portions 20 and 22, respectively, that are integrally connected to the body 18 and remain substantially stationary during operation of the valve. The leaflets 14 and 16 also include seal portions 24 and 26, respectively, that move between an open position as shown at 10 and a closed position as shown at 12.

[0019] A support ring 28 or other structure is preferably used to support the thin film body 18 and keep it stationary adjacent to the wall of the artery or lumen 30. The wall of the lumen 30 defines an opening 32 that has a periphery 34 and a center 36. Arrow 38 depicts the direction of fluid flow when the leaflets 14 and 16 are in an open position. Arrow 40 depicts the direction of flow that is prevented when leaflets 14 and 16 are in the closed position.

[0020] A second exemplary embodiment of a heart valve in accordance with the present invention is shown in FIG. 2. The heart valve is shown in the open position at 50 and the closed position at 52. The heart valve includes a thin film 53 of metal alloy that exhibits phase transformation and/or twin boundary motion. The thin film 53 is used to form two leaflets 54 and 56. The leaflets 54 and 56 of the thin film are integrally connected together at an anchor portion 58. The anchor portion 58 is attached to an anchoring structure 60. The anchoring structure 60 is attached securely to a valve body 62 to insure that the anchor portion 58 remains substantially stationary during operation of the valve. The leaflets 54 and 56 move between an open position as shown at 50 and a closed

position as shown at 52. The valve preferably includes a leaflet support (shown in phantom at 64) that supports the leaflets 54 and 56 and prevents buckling of the thin film when the valve is in the closed position.

[0021] The anchoring structure 60 and leaflet support 64 may be attached to the valve body 62 in a number of different ways provided that the anchoring portion of the leaflets remains stationary in the center of the artery or lumen 70 and the leaflets seal against the valve body 62. Arrow 72 depicts the direction of fluid flow when the leaflets 54 and 56 are in an open position. Arrow 74 depicts the direction of flow that is prevented when leaflets 54 and 56 are in the closed position.

[0022] A thin film in accordance with the present invention that is suitable for use in a valve of the type shown in FIG. 1 is shown at 100 in FIG. 3. The thin film includes three leaflets 102, 104 and 106. The thin film 100 also includes a body portion 108. Each of the leaflets includes a seal portion located at the top of the arc of each leaflet and an anchor portion that is integral with the body portion of the thin film. The thin film 100 is wrapped around and attached to a support ring or tube 110 to form a valve as shown at 112. The support tube 110 is preferably a mesh that is made from the same material as the thin film or a similar material. The tube 110 is preferably a self-expandable star-shaped framework of NiTi wire. The thin film 100 can be mounted in either a surgically placed frame with a dacron sewing ring or a stent for transcatheter insertion.

[0023] The valve 112 operates in the same manner as depicted in FIG. 1 except that there are three leaflets moving inward during valve closure instead of two. As is apparent, the number of leaflets may be increased provided that an effective seal is still obtained when the valve is closed. Although the leaflets shown in FIG. 3 have an arcuate shape, it is preferred that when three valve leaflets are used that each leaflet be in the shape of an equilateral triangle. It was discovered that triangular leaflets are particularly resistant to tearing. Although triangular shaped leaflets that are not equilateral may be used, it is preferred that the triangular leaflets be equilateral. For valves that utilize more than three leaflets, the shape of each leaflet may be the same or different than the other leaflets in the

valve. Preferably, in such multiple leaflet valves, each leaflet will have the same shape.

[0024] A thin film in accordance with the present invention that is suitable for use in a valve of the type shown in FIG. 2 is shown at 200 in FIG. 4C. The thin film 200 includes two leaflets 202 and 204 that have a common anchor portion 206. Each leaflet also includes a seal portion 208 and 210. The thin film 200 is sized and shaped to fit within a valve body 212 that is shown in FIG. 4A. An anchoring structure in the form of rods 214 and 216 are attached to the valve body 212. The thin film 200 is attached to the rods at the anchor portion 206 of the thin film to provide anchoring of the thin film within the valve body and the formation of the leaflets 202 and 204.

[0025] In order to insure adequate support and sealing of the leaflets 202 and 204, it is preferred that a leaflet support structure be included in the valve. An exemplary leaflet support structure is shown at 220 in FIG. 4B. The support structure 220 includes a sleeve 222 that fits inside valve body 212 to provide a ledge around the periphery of the body on which the leaflets are seated during valve closure (See FIGS. 5-7). In addition, support rods 224 extend across the sleeve 222 to support the leaflets when the valve is closed. The support rods are preferably made from the same material as the thin film or a similar material.

[0026] FIG. 5 is a partially assembled valve that includes sleeve 222 inserted within the valve body 212. The thin film 200 that forms the leaflets 202 and 204 is not shown so that the elements of the support and anchoring structures are more easily seen. The complete valve assembly, including the thin film 200, is shown in FIGS. 6 and 7. The valve is shown in the open position in FIG. 6 and in the closed position in FIG. 7.

[0027] The thin films 100 and 200 are made from thin films of metal alloys that are phase transforming and/or exhibit twin boundary motion. The thin films preferably have a thickness ranging from about 20 microns down to 5 microns or less. The film thickness will vary depending upon the specific valve type and may be as thick as 50 microns. In general, the thickness of the material must be such that the valve leaflets are sufficiently strong and flexible to provide valve opening and closure over relatively long periods of time at the pressures and flow

rates typically present in the human body. Film thickness on the order of about 10 microns is particularly preferred since this thickness provides a combination of high strength and continued flexibility that is a unique requirement for heart valves.

[0028] The present invention covers the use of thin-film metal alloys for both percutaneous and surgical valves as well as covered stents, artrial septal defect (ASD) closure devices (for primum and secundum ASD defects) and ventricular septal defect (VSD) closure devices. Material selection is very important in the case of mechanical heart valves. Materials used in heart valves must not cause an excessive inflammatory response, must not be toxic to the body, and should not cause clotting in the blood stream. NiTi is a preferred metal alloy for use in making the thin films and valves in accordance with the present invention. NiTi, a nickel-titanium alloy, is a well-known biocompatible material used in many implantible medical devices including stents and artrial septal defect occlusion devices. When implanted within blood vessels and within the heart itself, it has proven to be non-toxic, biocompatible and non-thrombogenic. Other non-metal alloy materials that are known to be biocompatible and suitable for use in heart valves may be used, if desired, to make the various parts of the valve other than the thin film leaflets.

[0029] The NiTi and the other metal alloys described below exhibit a thermally induced crystalline transformation between a ductile martensite phase at low temperatures and a rigid austenite phase at high temperatures. Upon cooling below the martensite temperature unstrained metal alloy has a twinned martensite structure. When placed under stress, the twin orientation is reorganized along the direction of stress. When heated above austenite temperature the material regains its rigid highly ordered austenite phase and recovers the original shape in which it was crystallized. In recovering their initial shape these metal alloys can produce high forces or large motion that translate directly to high pressure or large stroke. Properties similar to these allow devices made from these metal alloys to be compressed and delivered via catheters.

[0030] Any of the known metal alloys that exhibit phase transformation and/or twin boundary motion may be used to form the thin films for use in accordance

with the present invention. These metal alloys are referred to herein as "thin-film metal alloys". Exemplary thin-film metal alloys include: nickel-titanium alloys (NiTi); nickel-titanium-copper alloys (NiTiCu) and other copper-based alloys; gold-cadmium and other cadmium-based alloys (AuCd); nickel-titanium-platinum (NiTiPt) and other platinum-based alloys; nickel-titanium-palladium (NiTiPd) and other palladium-based alloys; nickel-titanium-hafnium (NiTiHf) and other hafnium-based alloys; and nickel-magnesium-gallium alloys (NiMgGa), nickel-manganese-gallium alloys (NiMnGa) and other gallium-based alloys.

[0031] Nickel-titanium alloys are preferred that contain about 50 atom percent nickel and about 50 atom percent titanium. Nickel-titanium alloys with other atom percentages are also preferred that include from 45 to 55 atom percent nickel and from 45 to 55 atom percent titanium.

[0032] FIG. 8 is a diagrammatic representation of an exemplary sputtering system that can be used to make thin films of metal alloy that have the thickness required for use in the valves of the present invention. The system includes a magnetron sputtering cathode 300, magnet assemblies 302 and metal alloy target material 304. The system is operated in the same manner as conventional magnetron sputtering equipment wherein a primary magnetic field 306 and electric field 304 are generated such that argon ions 310 are accelerated to the target 304 to eject surface atoms 312 from the target. The ejected atoms 312 travel to substrate 316 where they form a thin coating 314 that can be used to make valves in accordance with the present invention.

[0033] As an example, thin films of NiTi in accordance with the present invention can be produced in a sputter system as shown in FIG. 8 that is evacuated to a pressure below $5x10^{-8}$ Torr and back filled with argon to the desired deposition pressure. Using known direct current magnetron sputtering techniques, target nickel and titanium atoms are bombarded by an energetic argon ion that dislodges them. The percentage of the final nickel to titanium ratio is controlled by the composition of the initial substrate (target) and the sputtering profile. The dislodged nickel and titanium atoms subsequently condense on a custom-shaped four-inch by 500 micron silicon wafer target. A strong magnetic

field is used to concentrate the plasma near the target to increase the deposition rate. The amorphous deposited thin film is then crystallized at 500°C for 20 minutes in order to show shape memory/super-elastic behavior. In one embodiment, the film is deposited to form films like films 100 or 200 which are removed carefully from the silicon substrate. In the case of film 100, the film is fixed to a self-expandable framework of super-elastic NiTi wire such that three portions of the thin film membrane are free to function as valve leaflets.

[0034] Details of an exemplary magnetron sputtering system are as follows:

[0035] The system is made form modular parts that are available from vacuum suppliers such as Kurt J. Lesker, Duniway Stock Room, Physical Electronics and U.S. Thin Film Products. The system uses all metal Conflat flanges that compress copper gaskets to form a vacuum seal. The only elastomer seal is the VITON gasket on the door of the load lock. With the gate valve between the load lock, the chamber closed and a complete bakeout of the system, ultra high vacuum (UHV less than 10^{-8} Torr) can be achieved. A suitable load lock is available from MDC Vacuum Components. It has an 8-inch gate valve with a 6-inch diameter clearance and a linear transfer arm for placing 4-inch silicon substrates into the main chamber. The main chamber is a universal chamber that is available from Physical Electronics and which has multiple expansion ports.

[0036] A cryogenic pump is the primary pump of the system due to its ultra high vacuum capability in attaining pressures below 10^{-8} Torr. The cryogenic pump is considered a third stage pump requiring a vacuum better than 10^{-5} Torr before it can be turned on. The first stage and second stage pumps of the system are an Edwards RV5 mechanical pump and a Pfeiffer TU062 turbo pump, respectively. These pumps, attached to the load lock, pump the main chamber through the 8-inch gate valve between the load lock and the chamber.

[0037] Similar to the vacuum pumps, multiple vacuum gauges are required since there exists no single vacuum gauge with the ability to measure pressures in the range of atmospheric to 10^{-10} Torr. A thermocouple vacuum gauge with a range from atmospheric to 10^{-3} Torr is located at the load lock to measure the rough vacuum. The purpose of this gauge is to determine that a sufficient vacuum has

been reached prior to starting the turbo pump and the ion gage. A Bayard-Alpert style ion gauge, with a controller from Kurt J. Lesker, is located in the main chamber and can monitor pressures between 10^{-2} and 10^{-10} Torr. It is important to remember that the ion gauge cannot be activated at vacuums lower than 10^{-2} Torr since the filament will easily oxidize. To monitor the argon pressure during sputtering, a cold cathode gauge with a range of 10^{-2} to 10^{-7} Torr is used. These gauges are immune to filament burnout and harsh vacuum environments since they contain no filaments.

[0038] A Stanford Research residual gas analyzer (RGA) is present in the system to detect the gas pressures of any contaminants. It is functional at vacuums greater than 10^{-4} Torr and because it can measure specific gas pressures, it can also serve as a general vacuum gauge or leak detector. To determine the existence of any gasket leaks, helium is blown around the seals while monitoring the RGA for any spikes in the helium concentration. The primary use of the RGA, however, is to monitor what gases contribute to the base pressure prior to sputtering.

[0039] A 3-inch magnetron sputtering gun, manufactured by US Thin Film Products, Inc. is used in the system and is powered by a 1000W DC power supply from Advance Energy. Sputtering at 600 W is possible while maintaining good thermal contact using an iron backing plate and thermal paste. By using a nonferrous Cu backing plate and no thermal paste, the sputtering power is limited to 300W. The gun is cooled with a Neslab CFT-75 recirculating chiller that pumps 10°C water at 1.5 gal/min. If a flow rate of 1.5 gal/min is used with no thermal paste, the target begins to overheat after 15 minutes. At this point, the outer ring magnets lose magnetization causing the plasma to extinguish at low argon pressures. To maintain proper operating conditions, the inner magnet and outer ring magnet should register a magnetic flux of 3.0 kGauss and 1.6 kGauss, respectively.

[0040] Metal alloys in accordance with the present invention, such as thin-film NiTi, provide advantages in the construction of both surgically and percutaneously placed valves. In the cases of catheter-based valves, thin film metal alloy allows for the construction of a heart valve able to collapse to 2-3 mm

in diameter. Additionally, the shape-memory features of these metal alloys allow the device to expand and regain the form of a functional semi-lunar heart valve. Finally, the biocompatible and non-thrombogenic nature of the metal alloys also lends to advantages in the construction of this sort of valve.

[0041] Having thus described exemplary embodiments of the present invention, it should be noted by those skilled in the art that the within disclosures are exemplary only and that various other alternatives, adaptations and modifications may be made within the scope of the present invention. Accordingly, the present invention is not limited to the above preferred embodiments and examples, but is only limited by the following claims.

CLAIMS

What is claimed is:

1. A device designed for implantation into a body to control fluid flow through a lumen in said body, said device comprising:

at least one leaflet adapted to be located within said lumen, said leaflet comprising an anchor portion that remains substantially stationary within said lumen and a seal portion that is movable between an open position wherein fluid flow through said lumen in a given direction is allowed and a closed position wherein the flow of fluid through said lumen in a direction opposite to said given direction is restricted, said leaflet comprising a thin-film metal alloy that has a thickness which is less than 50 microns.

2. A device according to claim **1** wherein the thickness of said thin-film metal alloy is between 5 microns and about 20 microns.

3. A device according to claim **2** wherein the thickness of said thin-film metal alloy is about 10 microns.

4. A device according to claim **1** wherein said thin-film metal alloy is a nickel-titanium alloy.

5. A device according to claim **1** wherein said lumen into which said device is to be implanted includes a lumen wall that defines an opening having a periphery and a center and wherein said seal portion of said at least one leaflet moves towards the center of said opening when said leaflet moves to said closed position.

6. A device according to claim **5** wherein said device comprises at least three leaflets.

7. A device according to claim **5** wherein said device comprises a body portion that is connected to said one or more leaflets and wherein said body portion comprises a thin-film metal alloy film that has a thickness which is less than 50 microns.

8. A device according to claim **6** wherein said device comprises a body portion that is connected to said at least three leaflets and wherein said body portion comprises a thin-metal alloy that has a thickness which is less than 50 microns.

9. A device according to claim 7 wherein said body portion includes a support structure for the thin-metal alloy film present in said body portion.

10. A device according to claim **1** wherein said lumen into which said device is to be implanted includes a lumen wall that defines an opening having a periphery and a center and wherein said seal portion of said at least one leaflet moves towards the periphery of said opening when said leaflet moves to said closed position.

11. A device according to claim **10** wherein said leaflet comprises at least two leaflets.

12. A device according to claim **10** wherein said at least two leaflets have a common anchor portion.

13. A device according to claim **11** wherein said device includes a body portion comprising an anchoring structure for said leaflets wherein said anchoring structure extends across said opening and wherein the anchor portion of said leaflets are attached to said anchoring structure.

14. A device according to claim **14** wherein said device includes a support structure that provides support for said leaflets within said opening when said leaflets are in said closed position.

15. A film that is adapted for use in a device designed for implantation into a body to control fluid flow through a lumen in said body wherein said thin film is in a form that comprises at least one leaflet adapted to be located within said lumen, said leaflet comprising an anchor portion that remains substantially stationary within said lumen and a seal portion that is movable between an open position wherein fluid flow through said lumen in a given direction is allowed and a closed position wherein the flow of fluid through said lumen in a direction opposite to said given direction is restricted and wherein said film comprises a thin-film metal alloy that has a thickness which is less than 50 microns.

16. A film according to claim **15** wherein the thickness of said thin-film metal alloy is between 5 microns and about 20 microns.

17. A film according to claim **16** wherein the thickness of said thin-film metal alloy is about 10 microns.

18. A film according to claim **15** wherein said thin-film metal alloy is a nickel-titanium alloy.

19. A film according to claim **15** wherein said lumen into which said film is to be implanted includes a lumen wall that defines an opening having a periphery and a center and wherein said seal portion of said at least one leaflet moves towards the center of said opening when said leaflet moves to said closed position.

20. A film according to claim **19** wherein said film is in a form that comprises at least three leaflets.

21. A film according to claim **19** wherein said film is in a form that comprises a body portion that is connected to said one or more leaflets and wherein said body portion comprises a thin-film metal alloy that has a thickness which is less than 50 microns.

22. A film according to claim **20** wherein said film is in a form that comprises a body portion that is connected to said at least three leaflets and wherein said body portion comprises a thin-film metal alloy that has a thickness which is less than 50 microns.

23. A film according to claim **21** wherein said body portion includes a support structure for the portion of said film that is located in said body portion.

24. A film according to claim **15** wherein said lumen into which said film is to be implanted includes a lumen wall that defines an opening having a periphery and a center and wherein said seal portion of said at least one leaflet moves towards the periphery of said opening when said leaflet moves to said closed position.

25. A film according to claim **24** wherein said film comprises at least two leaflets.

26. A film according to claim **25** wherein said at least two leaflets have a centrally located common anchor portion.

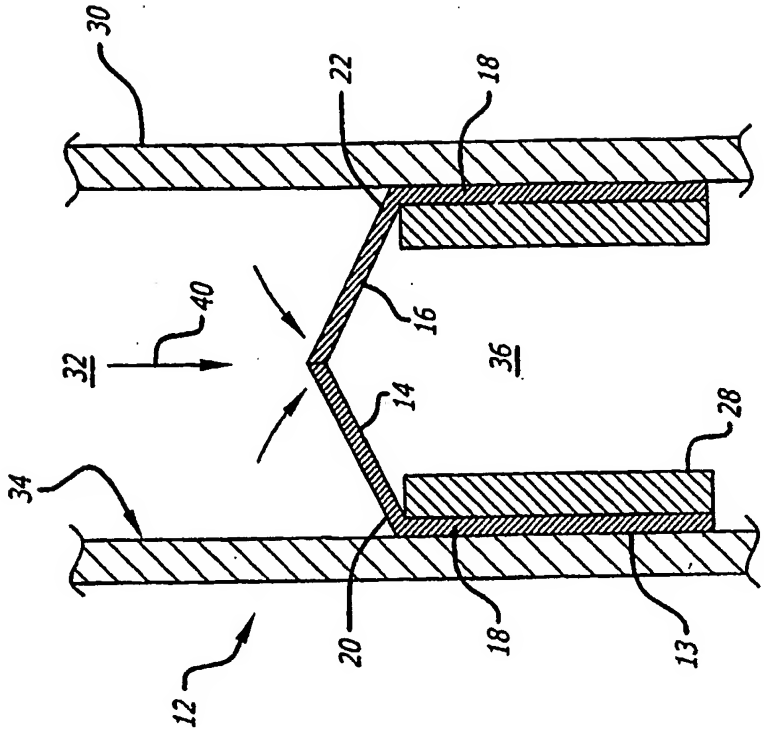
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FIG. 1B

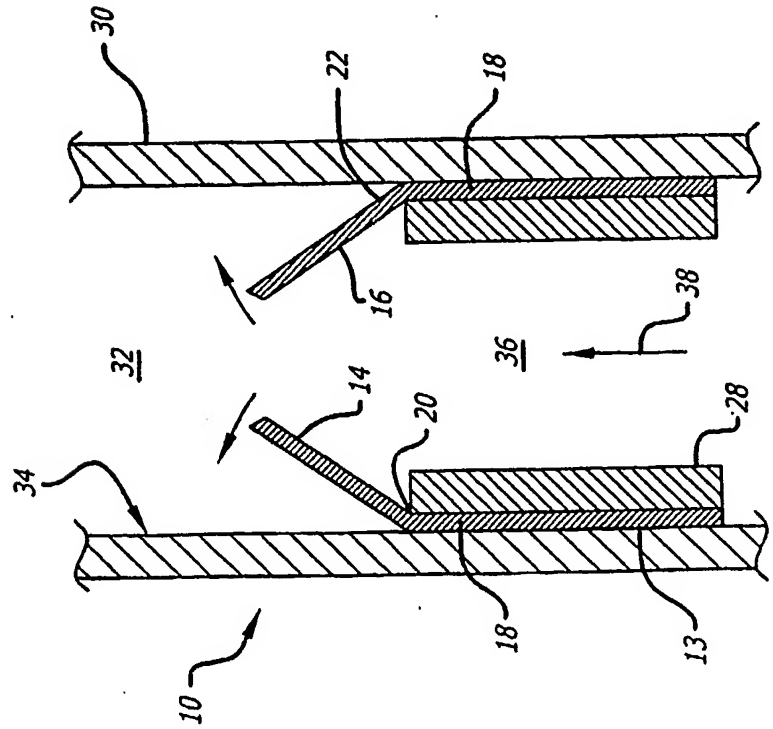
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FIG. 1A

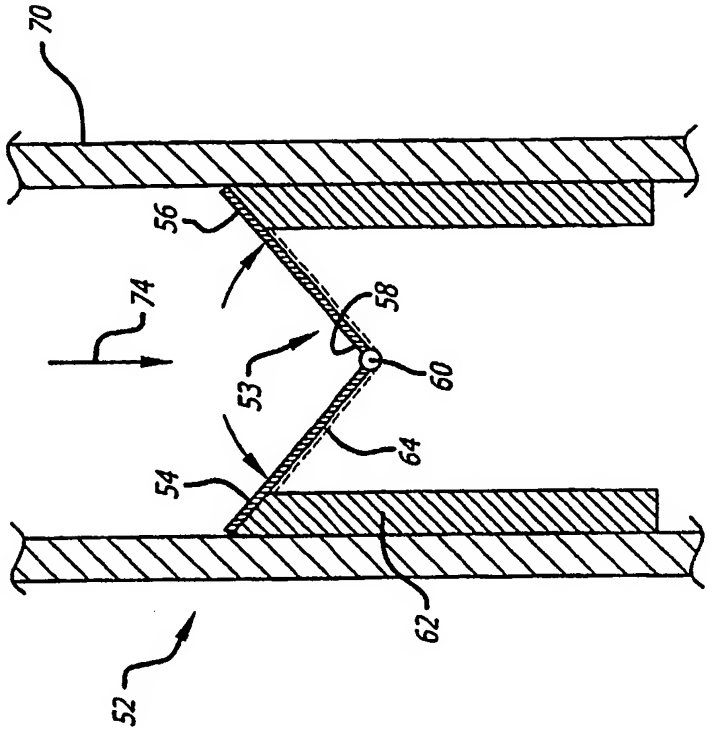

FIG. 2B

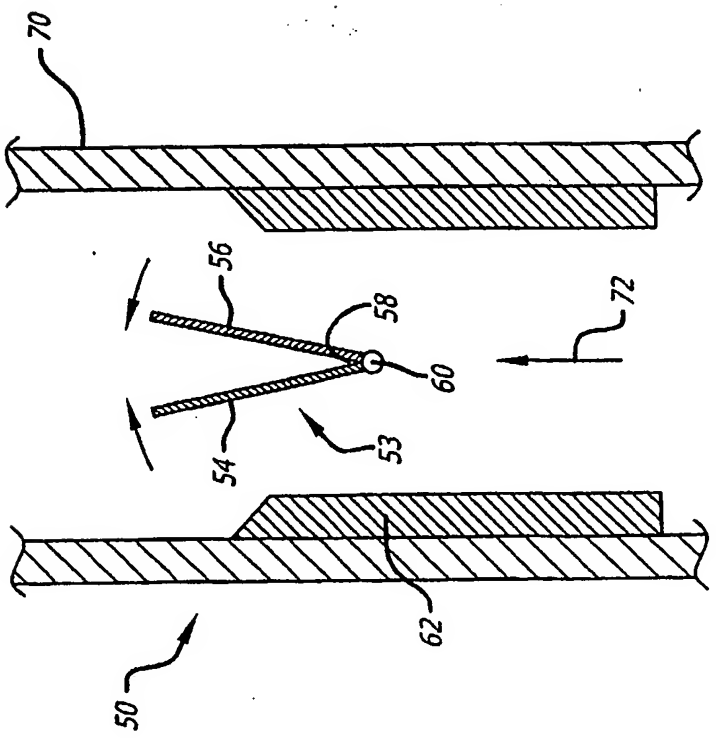

FIG. 2A

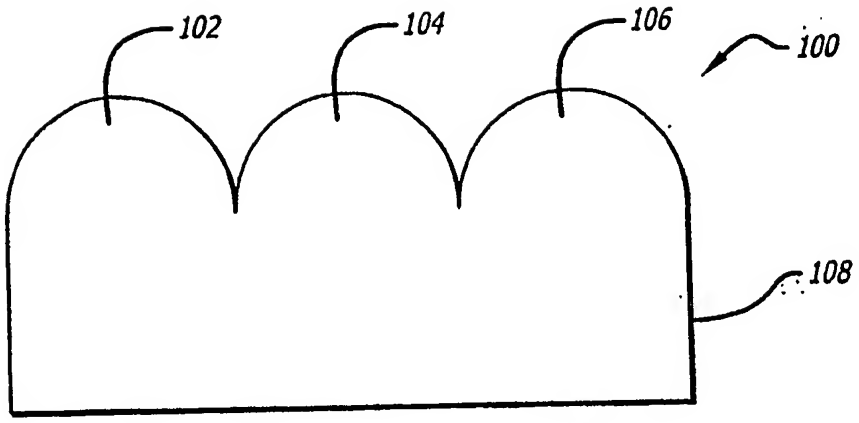

FIG. 3A

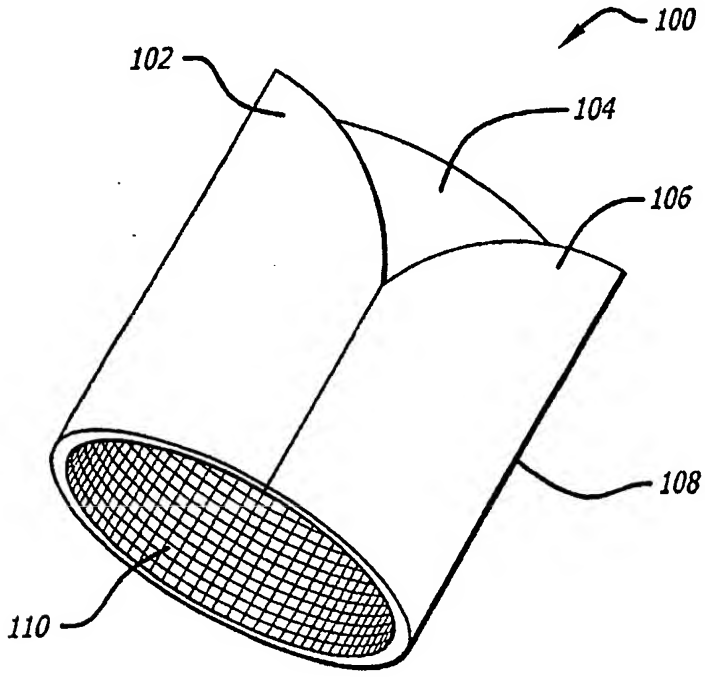

FIG. 3B

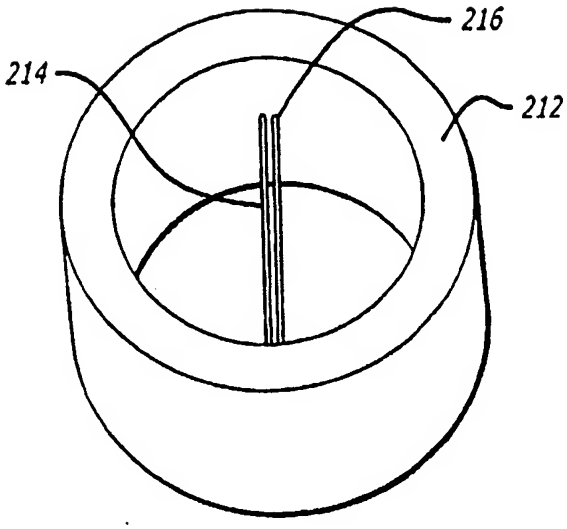

FIG. 4A

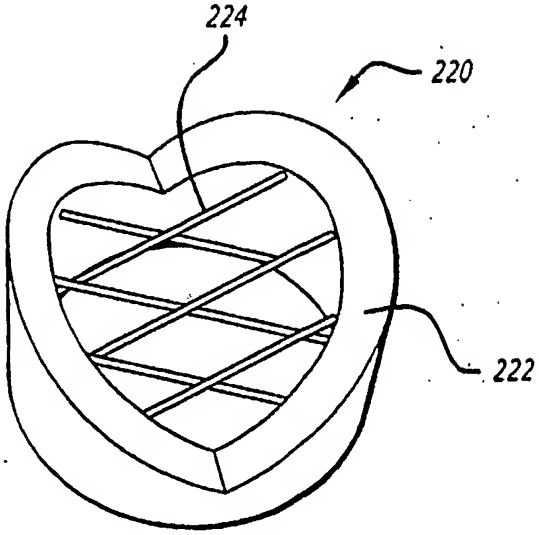

FIG. 4B

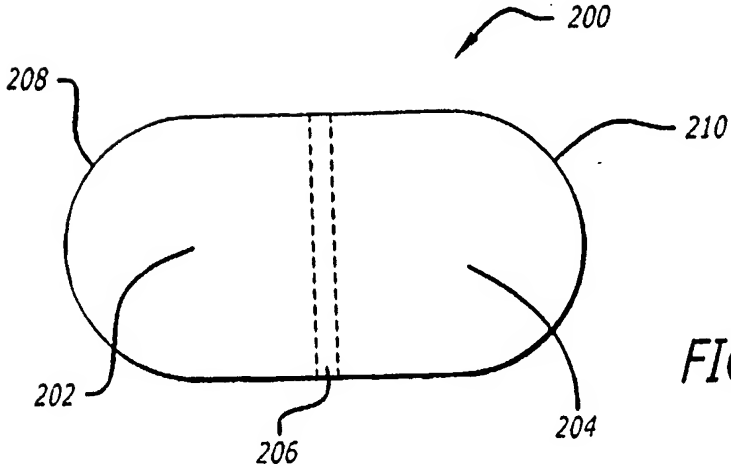

FIG. 4C

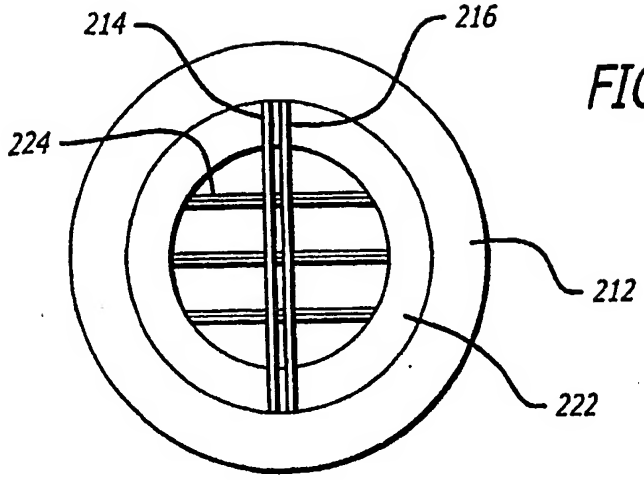

FIG. 5

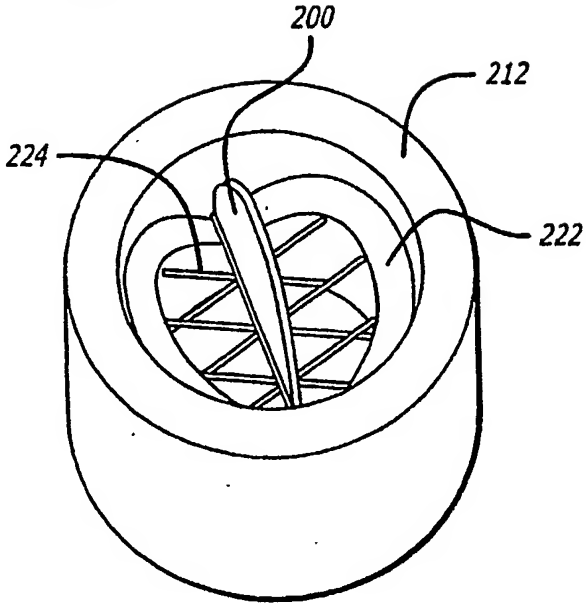

FIG. 6

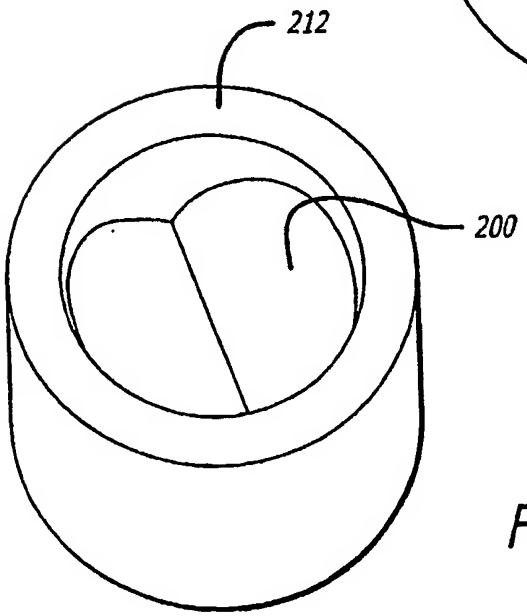

FIG. 7

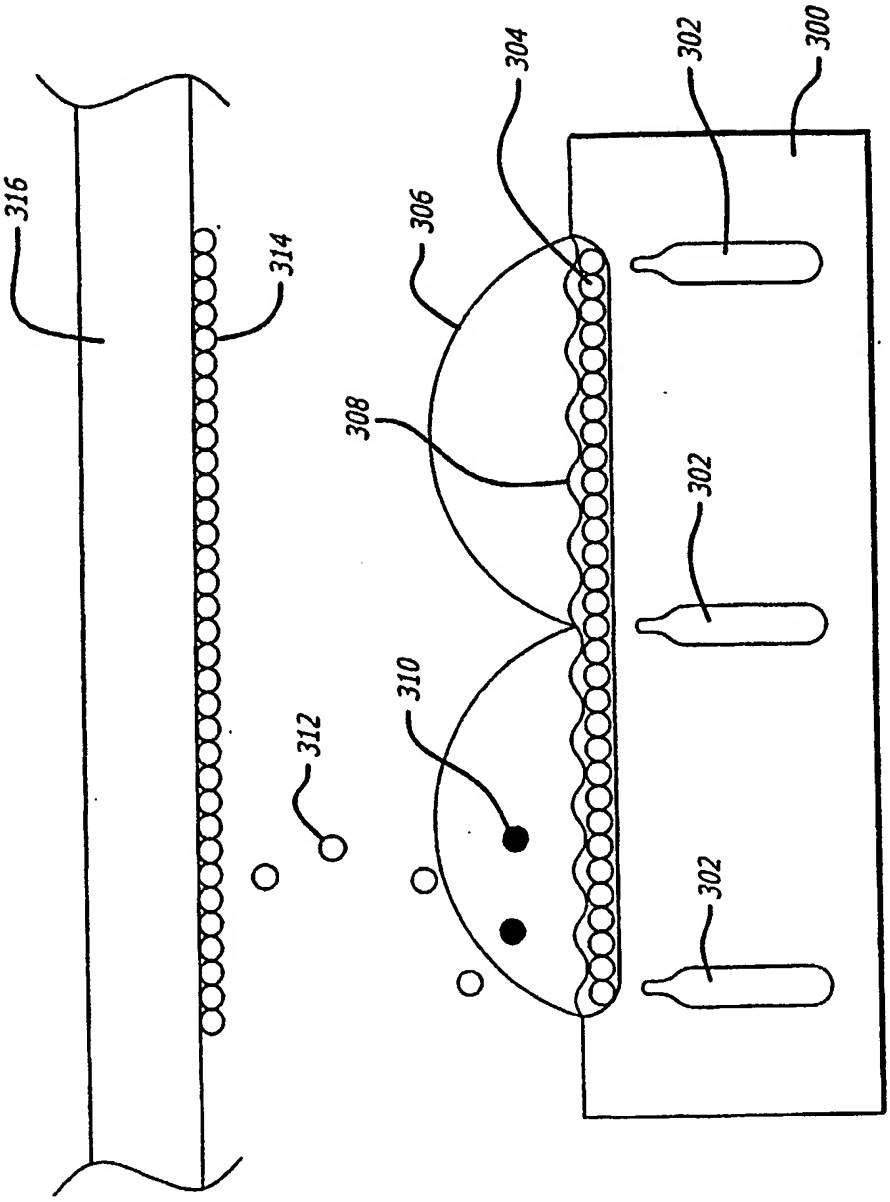

FIG. 8